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PRELIMINARY AMENDMENT
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Respectfully submitted,



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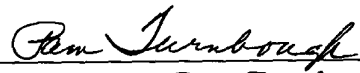
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Date: February 26, 2002

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Appendix I

Claims As Pending Upon Entry of Preliminary Amendment

1. (amended) The device of claim 30 wherein the biodegradable polyhydroxyalkanoate composition has a controlled degradation rate of less than two years under physiological conditions, wherein the degradation rates of the polyhydroxyalkanoates are manipulated through addition of components to the polymeric composition, selection of the chemical composition, molecular weight, processing conditions, or form of the composition.

2. (amended) The device of claim 1 wherein the chemical composition of the polyhydroxyalkanoate is altered through selection of monomers which are incorporated into the polymer, by alteration of the linkages, chemical backbone or pendant groups, or by manipulation of the molecular weight.

3. (amended) The device of claim 1 wherein the polyhydroxyalkanoate composition comprises additive altering the degradation rate of the composition, wherein the additives are selected from the group consisting of hydrophilic substances, hydrophobic substances, and coating which alter water uptake by the composition.

4. (amended) The device of claim 1 wherein the polyhydroxyalkanoate comprises a polymer selected from the group of consisting of poly-4-

hydroxybutyrate, poly-4-hydroxybutyrate-co-3-hydroxybutyrate, poly-4-hydroxybutyrate-co-2-hydroxybutyrate, and copolymers and blends thereof.

5. (amended) The device of claim 1 wherein the polyhydroxyalkanoate comprises a polymer selected from the group consisting of poly-3-hydroxybutyrate-co-3-hydroxyhexanoate, poly-3-hydroxybutyrate-co-3-hydroxyoctanoate, poly-3-hydroxybutyrate-co-3-hydroxydecanoate, and copolymers and blends thereof.

6. (amended) The device of claim 1 wherein the polyhydroxyalkanoate comprises one or more units which alter the chemical stability of the polymer backbone.

7. (amended) The device of claim 1 comprising unit(s) promoting chain scission.

8. (amended) The device of claim 7 wherein the units contain more than two functional groups.

9. (amended) The device of claim 1 wherein a heteroatom is incorporated into the polymer backbone chain.

10. (amended) The device of claim 9 wherein the heteroatom is selected from the group consisting of oxygen, sulfur or nitrogen.

11. (amended) The device of claim 7 wherein the units are incorporated into the polymer backbone with chemical linkages selected from the group consisting of ester, amide, ether, carbamate, anhydride, and carbonate.

12. (amended) The device of claim 11 wherein the units are selected from the group consisting of 2-hydroxyacids, 2-hydroxyalkoxyacetic acids, amino acids, amino alcohols, diacids, triols, and tetraols.

13. (amended) The device of claim 12 wherein the 2-hydroxyacids are 2-hydroxyalkanoic acids.

14. (amended) The device of claim 13 wherein the 2-hydroxyalkanoic acid is lactic acid or glycolic acid.

15. (amended) The device of claim 12 wherein the 2-hydroxyacids are 2-hydroxyalkenoic acids.

16. (amended) The device of claim 12 wherein the 2-hydroxyalkoxyacetic acids are selected from the group consisting of 2-hydroxyethoxy acetic acid and 3-hydroxypropoxy acetic acid.

17. (amended) The device of claim 1 wherein the polymer comprises pendant groups that catalyze the degradation of the polymer backbone.

18. (amended) The device of claim 17 wherein the pendant groups are selected from acidic and basic groups.

19. (amended) The device of claim 17 comprising reactant pendant groups that cause polymer chain scission.
20. (amended) The device of claim 19 wherein the reactant pendant groups are selected from nucleophiles and electrophiles.
21. (amended) The device of claim 17 wherein the pendant groups are selected from the group consisting of alcohols, acids, and amine groups.
22. (amended) The device of claim 1 comprising additives altering the chemical stability of the polyhydroxyalkanoate.
23. (amended) The device of claim 22 wherein the additives promote chain scission.
24. (amended) The device of claim 22 wherein the additives are selected from the group consisting of acids, bases, electrophiles, nucleophiles, plasticizers, polymers, pore forming agents, and agents designed to reduce the polymer crystallinity.
25. (amended) The device of claim 1 comprising pore forming agents.
26. (amended) The device of claim 25 wherein the pore forming agents are lyophilizable particles.
27. (amended) The device of claim 25 wherein the pore forming agents absorb water.

28. (amended) The device of claim 1 further comprising one or more active agents.

29. (amended) The device of claim 28 wherein the active agent is selected from the group consisting of growth factors, alginates, silver salts, antiseptics, analgesics, and preservatives.

30. A device comprising a biodegradable polyhydroxyalkanoate composition that has a controlled degradation rate of less than two years, preferably less than one year, under physiological conditions,

wherein the degradation rates of the polyhydroxyalkanoates are manipulated through addition of components to the polymeric composition, selection of the chemical composition, molecular weight, processing conditions, or form of the composition, as defined by any of claims 1-29,

wherein the device is selected from the group consisting of sutures, suture fasteners, meniscus repair devices, rivets, tacks, staples, screws, bone plates and bone plating systems, surgical mesh, repair patches, slings, cardiovascular patches, orthopedic pins, adhesion barriers, stents, guided tissue repair/regeneration devices, articular cartilage repair devices, nerve guides, tendon repair devices, atrial septal defect repair devices, pericardial patches, bulking and filling agents, vein valves, bone marrow scaffolds, meniscus regeneration devices, ligament and tendon grafts, ocular cell implants, spinal

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fusion cages, skin substitutes, dural substitutes, bone graft substitutes, bone dowels, wound dressings, and hemostats.

31. (amended) A method for making a device that has a controlled degradation rate of less than two years, more preferably less than one year under physiological conditions, comprising

providing comprising a biocompatible polyhydroxyalkanoate composition, as defined by claim 1, and

forming or incorporating the polyhydroxyalkanoate composition into a device selected from the group consisting of sutures, suture fasteners, meniscus repair devices, rivets, tacks, staples, screws, bone plates and bone plating systems, surgical mesh, repair patches, slings, cardiovascular patches, orthopedic pins, adhesion barriers, stents, guided tissue repair/regeneration devices, articular cartilage repair devices, nerve guides, tendon repair devices, atrial septal defect repair devices, pericardial patches, bulking and filling agents, ligament and tendon grafts, ocular cell implants, spinal fusion cages, skin substitutes, dural substitutes, bone graft substitutes, bone dowels, heart valves and vascular grafts, wound dressings, and hemostats.

32. The method of claim 31 wherein the processing forming or incorporating process is selected from the group consisting of solvent casting, melt processing, fiber processing, fiber spinning, fiber weaving, extrusion,

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Please cancel claim 34.

end 33

Marked-up Copy of Amended Specification Pages
Pursuant to 37 C.F.R. § 1.121(b)(1)(iii)

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MEDICAL DEVICES AND APPLICATIONS OF POLYHYDROXYALKANOATE POLYMERS

Cross-Reference To Related Applications

5 [Priority is claimed] This application is a divisional of pending prior application U.S. Serial No. 09/535,146 filed March 24, 2000, which claims priority to U.S. Serial No. 60/142,238, filed July 2, 1999, and U.S. Serial No. 60/126,180, filed March 25, 1999.

Field of the Invention

10 The present invention generally relates to polyhydroxyalkanoate ("PHA") biopolymers and medical uses and application of these materials.

Background of the Invention

In the medical area, a number of degradable polymers have been developed that break down *in vivo* into their respective monomers within weeks
15 or a few months. Despite the availability of these synthetic degradable polymers, there is still a need to develop degradable polymers which can further extend the range of available properties, particularly mechanical properties.

Polyhydroxyalkanoates are natural, thermoplastic polyesters and can be processed by traditional polymer techniques for use in an enormous variety of
20 applications, including consumer packaging, disposable diaper linings and garbage bags, food and medical products. Initial efforts focused on molding applications, in particular for consumer packaging items such as bottles, cosmetic containers, pens, and golf tees. U.S. Patent Nos. 4,826,493 and 4,880,592 describe the manufacture of poly-(R)-3-hydroxybutyrate ("PHB") and
25 poly-(R)-3-hydroxybutyrate-co-(R)-3-hydroxyvalerate ("PHBV") films and their use as diaper backsheet. U.S. Patent No. 5,292,860 describes the manufacture of the PHA copolymer poly(3-hydroxybutyrate-co-3-hydroxyhexanoate) and the use of these polymers for making diaper backsheet film and other disposable items. Diaper back sheet materials and other materials for manufacturing
30 biodegradable or compostable personal hygiene articles from PHB copolymers other than PHBV are described in PCT WO 95/20614, WO 95/20621, WO